

**REMARKS/ARGUMENTS**

This is in response to the Final Office Action mailed June 1, 2006. Claims 8-28 are pending in the application. Claims 10-13, 15-17, 21-24 and 26-28 are withdrawn from consideration. Claims 8-9, 14, 18-20 and 25 are pending for consideration.

Claims 8 and 18 have been amended to correct minor typographical errors. Claim 8 has also been amended to provide the full chemical name for "DCC", as requested by the Examiner. Claim 8 now includes the phrase "deleted in colorectal carcinoma (DCC)". Applicant believes that this amendment addresses the Examiner's request to provide the full chemical name for DCC at least once in the claims.

The Examiner has rejected claims 8-9, 14, 18-20 and 25 under 35 U.S.C. 103(a) stating that the claims are unpatentable over Kuehne et al. (CA 1 268 714, 1990) in view of Kern et al. (US 5 712 097).

The Examiner states that Kuehne et al. teaches a stabilized chlorite solution and its use in cancer treatment (e.g. metastatic solid tumors such as primary or metastatic adenocarcinoma). The Examiner proceeds to acknowledge that the claims differ from Kuehne et al. in that they are directed to pancreatic carcinoma. However, the Examiner states that Kern et al. teaches that a primary pancreatic carcinoma is adenocarcinoma that is associated with DCC. The Examiner therefore concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute adenocarcinoma with pancreatic carcinoma and that the recitation "the carcinoma characterized in DCC" is inherently possessed.

Further, the Examiner states that "One would have been motivated to make such substitution, with reasonable expectation of success, because the

effectiveness of chlorite solution against pancreatic cancer is well proven by CA'714, and it is always desired to extend the medical utility by substituting the effective therapy modality. Since the effectiveness is well proven and clearly suggested by CA'714, such substitution to include pancreatic carcinoma would increase industrial applicability and maximize the benefits of drug treatment against cancer therapy." The Examiner concludes that one would have been motivated to combine the cited references and make the modifications because they are drawn to the same technical field.

Applicant respectfully disagrees for the reasons outlined below.

Applicant submits that there is no teaching or suggestion in either of the cited references to combine the teachings to result in Applicant's claimed subject matter.

It is well established that, in order to sustain a rejection under 35 U.S.C. §103, it is the burden of the USPTO to establish a *prima facie* case of obviousness, *In re Reuter*, 651 F.2d 751, 210 U.S.P.Q. 249 (CCPA 1981). In asserting such a case of obviousness, the Examiner must propose some modification of a particular reference or a combination thereof with another reference in order to arrive at the claimed invention. In this regard, the teachings of a single prior art reference or a primary prior art reference (which is combined with one or more secondary prior art references) must be sufficient to justify a conclusion that any proposed modification or combination of references is what one of ordinary skill in the art would have found obvious to do at the time the invention was made, *In re Linter*, 458 F.2d 1013, 173 U.S.P.Q. 560, 562 (CCPA 1972). Moreover, the Courts have held that there must be some logical reason apparent from the evidence of record that would justify a modification or combination of prior art references, *In re Regel*, 188 U.S.P.Q. 132 (CCPA 1975). If there is no such reason, the *prima facie* case of obviousness has not been

made out, Oscar Mayer Foods Corp. v. Sara Lee Corp. 15 U.S.P.Q. (2d) 1204, (D.C.Wis., 1990).

Hindsight combination of references is not a valid basis for rejection under 35 U.S.C. §103, In re Adams, 148 U.S.P.Q. 742 (CPPA 1966) and In re Skoll, 187 U.S.P.Q. 481, 484 (CCPA 1975). Further in Twin Disc Inc. v. United States, 10 Cl. Ct. 713; 231 U.S.P.Q. 417, 425 (Cl. Ct 1986), the Court stated:

“... it is now clear beyond cavil that it is not permissible to ascertain factually what the inventors did and then view the prior art in such a manner as to select from the random facts of that art only those which may be modified and then utilized to reconstruct the claimed invention.”

Citing Orthopedic Equipment Co., Inc. v. United States, 702 F.2d 1005, 1012; 217 U.S.P.Q. 193, 199 (Fed. Cir. 1983) the Court in Twin Disc further stated that it is incorrect to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.

Applicant submits that the Examiner's suggestion that a motivation would have existed to combine these references because “..it is always desired to extend the medical utility by substituting the effective therapeutic modality” is improper based on well established case law. Further, there is no teaching or suggestion in Kuehne et al. to use the stabilized chlorite solution in the treatment of pancreatic carcinoma. Further, there is no teaching or suggestion in Kern et al. to a treatment for pancreatic carcinoma. Applicant submits that a person skilled in the art would not merely combine two distinct references, one being directed to the use of an aqueous chlorite solution for the treatment of tumors and the other being directed to polynucleotide and polypeptide sequences

encoding a novel suppressor gene, in the hopes that a new treatment for pancreatic carcinoma would result.

The Examiner previously stated in the office action dated February 8, 2006 that:

“As evidenced by numerous patent and no-patent literature, there is no single drug can treat all types of cancers, see US5721267 or US5676924. Since this assertion is contrary to what is known in medicine, proof must be provide[d] that this revolutionary assertion has merits. The existence of such a “silver bullet” is contrary to our present understanding of pharmacology (“New cancer drugs no “Magic bullet”, but promising”, Reuters News, 2001)”

Therefore Applicant submits that if, as per the Examiner’s suggestion, there is a general understanding in the field of cancer drugs, that there is no single drug that can treat all types of cancer, a person skilled in the art would not combine two distinct references in the mere hope of extending the medical utility of a solution taught in one of the references. Further, following the Examiner’s previous statements, a person skilled in the art would not have “...a reasonable expectation of success...” based on the Examiner’s statements recited above.

Applicant therefore submits that there is no motivation in either of the cited references to combine these two references to result in Applicant’s claimed subject matter. Applicant therefore requests withdrawal of the objection raised under 35 U.S.C. 103(a).

**CONCLUSION**

In light of the above amendments and comments, Applicant respectfully requests that all rejections and objections be withdrawn and that a timely Notice of Allowance should be issued in this application. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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